

Notice of Allowability

Application No.

09/920,517

Examiner

Q. Janice Li

Applicant(s)

CLARKE ET AL.

Art Unit

1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 1/28/05.
2. ☒ The allowed claim(s) is/are 1,4,6,8-14,18-23,28-30,32,34,35,38,40,188,194 and 199-210.
3. ☒ The drawings filed on 01 August 2001 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

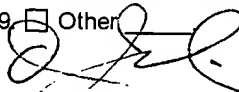
* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date 1/28/05
4. ☐ Examiner's Comment Regarding Requirement for Deposit
of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☒ Interview Summary (PTO-413),
Paper No./Mail Date _____
7. ☒ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other



Q. JANICE LI, M.D. Primary Examiner
PRIMARY EXAMINER Art Unit: 1632

DETAILED ACTION

This action is in response to the Amendment and response filed January 28, 2005. Claims 1, 23, 32 have been amended. All of the amendments have been thoroughly reviewed and entered. The previous rejections of the Office action mailed 12/1/04 are withdrawn in view of the amendments.

Claims 1, 4, 6, 8-14, 18-23, 28-30, 32, 34, 35, 38, 40, 188, 194, 199-210 are under current examination.

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with David Casimir on March 14, 2005.

The claims have been amended as follows:

In claim 14, --stem-- was inserted before "cells" in line 3.

Claim 23. (currently amended) An enriched population of solid tumor stem cells obtained from a solid tumor of epithelial origin, ~~comprising~~ wherein said population

comprises: solid tumor stem cells and solid tumor cells, wherein the solid tumor stem cells:

- (a) are enriched at least two-fold compared to unfractionated tumor cells;
- (b) are tumorigenic;
- (c) express CD44;
- (d) do not express detectable levels of one or more LINEAGE markers selected from the group consisting of CD2, CD3, CD10, CD14, CD16, CD31, CD45, CD64, and CD140b; and
- (e) do not express CD24 or express low levels of CD24; and
wherein the solid tumor cells are non-tumorigenic.

Claims 4, 6, 8-14, 18-23, 28-30, 32, 34, 35, 38, 40, 188, 194, 199-210 have been renumbered as claims 2-38 according to 37 C.F.R. 1.126 (see MPEP 608.01 (j) and 608.01 (n)/IV).

Conclusion

Claims 1, 4, 6, 8-14, 18-23, 28-30, 32, 34, 35, 38, 40, 188, 194, 199-210 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Q. Janice Li** whose telephone number is 571-272-0730.

The examiner can normally be reached on 9:30 am - 7 p.m., Monday through Friday, except every other Wednesday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Ram R. Shukla** can be reached on 571-272-0735. The fax numbers for the organization where this application or proceeding is assigned are **571-273-8300**.

Any inquiry of formal matters can be directed to the patent analyst, **Dianiece Jacobs**, whose telephone number is (571) 272-0532.

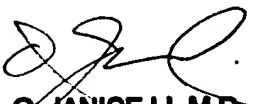
Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It

Art Unit: 1632

also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

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Art Unit 1632

QJL
March 10, 2005